

In re Application of:  
Hugli and Jackson  
Application No.: 09/922,236  
Filed: August 2, 2001  
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Atty Docket No.: SCRIP1460

### REMARKS

Claims 1-4, 14 and 25-26 have been amended. Claims 10 and 35 were previously cancelled without prejudice. Claims 13, 17, 20-24, 38 and 47-72 were previously withdrawn. The Office Action stated that claims 1-9, 11-34 and 36-72 were pending. However, as stated above and in the listing of the claims, claims 10 and 35, and claims 13, 17, 20-24, 28 and 47-72 were previously canceled or withdrawn. Hence, claims 1-9, 11-12, 14-16, 18-19, 25-34, 36-37 and 39-46 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

#### **I. Amendment to the Claims**

Claims 1-3, 14 and 25-26 have been amended. The Office Action mailed June 16, 2005, stated that "only one kallikrein-like peptidase species has been described, that is actually kallikrein (the paragraph bridging pages 2 and 3)". Without conceding to the correctness of the rejection, but to further advance the prosecution of the above application, the claims have been amended to delete the phrase "kallikrein-like peptidase" and replace it with the term "kallikrein".

Support for the amendment can be found in the specification and original claims, for example, Example 1, FIGs. 6-10, and original claims 2, 26, 49 and 63. Therefore, no new matter has been added.

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**II. Rejections under 35 U.S.C. §112, First Paragraph (written description)**

Claims 1-3, 5-9, 11-12, 14-16, 18-19, 25-34, 36-37 and 39-46 stand rejected under on 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection as it applies to the amended claims.

According to the Office Action, Applicant the phrase “kallikrein-like peptidase” is not adequately described in the specification (page 2 of the Office Action).

Claims 1-4, 14 and 25-26 have been amended as discussed above, and the phrase “kallikrein-like peptidase” has been deleted and replaced with the term “kallikrein”. As discussed above, the claim amendments are fully supported in specification and original claims and no new matter has been added. The amendments were made to advance prosecution of the above application and not to concede the correctness of the rejection. Thus, the claims are sufficiently described in the application as filed, e.g., see Example 1, FIGs. 6-10 and original claims.

Accordingly, withdrawal of rejection of claims 1-3, 5-9, 11-12, 14-16, 18-19, 25-34, 36-37 and 39-46 under 35 U.S.C. § 112, first paragraph is respectfully requested.

**III. Rejections under 35 U.S.C. § 102(a)**

Claims 1-3, 5-12, 14, 16 and 18-19 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Hayashi & Hugli (*Protein Science Abstract*, 2000). Applicants respectfully traverse the rejection as it applies to the amended claims.

According to the Examiner, the Hayashi & Hugli Abstract is still by “another” because the Declaration attached to the response and filed September 16, 2005 does not state reasons why Hayashi is not an inventor and why Jackson is not an author of the Abstract.

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It is submitted that the Office's reasoning for not withdrawing the rejection is improper for the following reasons. First, Applicants submitted proper 37 CFR §1.132 Declarations under the circumstances and as provided by the MPEP and patent rules. Second, the legal concept of "inventorship" is well established, and distinguished from that of authorship of an abstract. Lastly, the Hayashi and Hugli abstract cannot anticipate the claimed invention, because the abstract does not disclose "each and every" element.

With regards to when is it proper to submit a 37 C.F.R. §1.132 Declaration, MPEP §716.10 which states that, "[u]nder certain circumstances an affidavit or declaration may be submitted which attempts to attribute an activity, *a reference* or part of a reference *to the applicant* (emphasis added)". One circumstance is stated in MPEP §715.01(c):

Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37 C.F.R. 1.131. Alternatively, the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 C.F.R. 1.132 establishing that the article is describing applicant's own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. 102(a) (emphasis added). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

The MPEP further provides Examples where a 37 C.F.R §1.132 Declaration is sufficient to overcome a 35 U.S.C. §102(a) rejection, MPEP §716.10 states:

**Example 1**

During the search the examiner finds a reference fully describing the claimed invention. The applicant is the author or patentee and it was published or patented less than one year prior to the filing date of the application. The reference cannot be used against applicant since it does not satisfy the 1-year time requirement of 35 U.S.C. §102(b).

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**Example 2**

Same facts as above, but the author or patentee is an entity different from applicant. Since the entities are different, the reference is prior art under 35 U.S.C. §102(a) or (e).

In the situation described in Example 2, an affidavit under 37 C.F.R §1.132 may be submitted to show that the relevant portions of the reference originated with or were obtained from applicant.

Applicants submit a Declaration by Dr. Tony E. Hugli and Dr. Craig Jackson enclosed herein. The Declaration herein and filed on September 16, 2005 are both proper according to 37 C.F.R §1.132 and the guidelines of the MPEP. The Declarations state that relevant portions of the Hayashi & Hugli reference originated with or were obtained from Dr. Hugli (see paragraph 5), and the Declaration enclosed herein further states “that Dr. Tony E. Hugli alone is the sole inventor of the subject matter of the Abstract, and that the other co-author, Joichiro Hayashi, was merely working under Dr. Hugli’s direction”. Thus, while Hayashi’s contribution was that of a co-author, it did not rise to the level of an inventor. Therefore, as stated in the MPEP and *In re Katz*, the Declarations alone are “sufficient to remove the publication as a reference under 35 U.S.C. 102(a)”.

Also, with regards to who is an “inventor” versus who is an “author”, at least the concept of “inventorship” is well established. “The threshold question in determining inventorship is who conceived the invention. ...One *must contribute to the conception to be an inventor* (emphasis added).” *In re Hardee*, 223 USPQ 1122, 1123 (Comm’r Pat. 1984). MPEP §2137.01. It is also well established that, “[c]onception has been defined as ‘the complete performance of the mental part of the inventive act’ and it is ‘the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice’”. *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930). MPEP §2138.04. Whereas, what determines “authorship” is not necessarily the “conception”

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threshold, or that it be someone who has formed “a definite and permanent idea of the complete and operative invention”. Thus, given these distinctions, the fact that authorship of the abstract and the inventorship of the claimed invention are different, is not cause to reject the invention so long as Applicants have properly declared that the abstract is their work in a 37 C.F.R. §1.132 Declaration.

Additionally, “each and every” element of the claimed invention must be disclosed in the single prior art. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131. It is submitted, that the Hayashi and Hugli abstract does not disclose “each and “every” element of the claimed invention because it does not disclose that kallikrein levels are indicative of liver damage due to hepatitis infection. Hayashi and Hugli disclose kallikrein levels are indicative of early stage tissue in the *transplanted* liver organ (see first and last sentence of the abstract). Thus, the Hayashi and Hugli abstract cannot anticipate the claimed invention.

Accordingly, withdrawal of rejection of claims 1-3, 5-12, 14, 16 and 18-19 under 35 U.S.C. § 102(a), first paragraph is respectfully requested.

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### Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

A check in the amount of \$395.00 is enclosed as payment for the Request for Continued Examination fee. No other fees are deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

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